IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., AND BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM ,	)	
Plaintiffs,	)	Civil Action No. 14-CV-2357-SHS
v.	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

DEFENDANT'S STATEMENT OF THE ELEMENTS
OF CLAIMS AND DEFENSES AND SUMMARY OF FACTS

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I. INTRODUCTION

The Court is already familiar with the sole patent-in-suit, U.S. Patent No. 6,488,963 ("the '963 patent"). Evidence on the invalidity of the '963 patent was admitted in *Purdue v. Teva I* ((11-cv-2400 (Impax); 11-cv-4694 (Sandoz); 12-cv-0897 (Sandoz); 12-cv-5082 (Sandoz); 12-cv-7582 (Sandoz); 11-cv-2037 (Teva); and 12-cv-5083 (Teva)). As such, the Court ordered that it has heard fulsome evidence on the issue of the alleged invalidity of the '963 patent during the trial of *Purdue v. Teva I*, and that only upon a showing of good cause may additional evidence of validity or invalidity be admitted in this action. (Order dated June 23, 2014, and filed June 24, 2014 (Dkt. No. 35) ("the Order").) Accordingly, Teva relies on the portions of Defendants' Statement of the Elements of Claims and Defenses and Summary of Facts dated September 13, 2013 submitted in *Purdue v. Teva I* ("the *Purdue v. Teva I* Statement of Elements and Defenses") relating to the invalidity of the '963 patent identified below.

With respect to infringement, Plaintiffs assert that Teva infringes claim 6, the sole asserted claim of the '963 patent. The evidence will show that the manufacturing process used to make Teva's controlled release dosage form is a traditional, decades-old process that does not use the hot-melt extrusion process of claim 6 or an equivalent process that performs substantially the same function, in substantially the same way, and with substantially the same result.

II. LEGAL STANDARDS

A. Infringement

Plaintiffs bear the burden to prove by a preponderance of the evidence that the products Teva seeks to sell pursuant to its ANDA will meet each and every element of Claim 6 of the '963 patent. Plaintiffs must show that Teva performs "each and every step or element of a claimed

method or product" to prove direct, literal infringement. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1320 (Fed. Cir. 2009) (internal quotation marks and citations omitted).

A product that does not literally infringe a claim may, under certain circumstances, infringe under the doctrine of equivalents if an "equivalent" of *every* element of the claimed invention is found in the accused product or method. *See Scanner Techs. Corp. v. Icos Vision Sys. Corp., N.V.*, No. 00 CIV. 4992 (DC), 2003 WL 196165, at *2-3. The patentee must prove "that the difference between the claimed invention and the accused product or method was insubstantial or that the accused product or method performs the substantially same function in substantially the same way with substantially the same result as each limitation of the patented product or method." *AquaTex Indus., Inc. v. Techniche Solutions*, 479 F.3d 1320, 1326 (Fed. Cir. 2007). The "failure to demonstrate equivalency for *any* single element in the accused [product] is enough to defeat an assertion of infringement under the doctrine of equivalents." *Robinson v. Fakespace Labs, Inc.*, No. 02-1152, 2003 WL 858911, at *3 (Fed. Cir. Mar. 5, 2003) (emphasis added).

B. Invalidity

Pursuant to the Order, Teva relies on and incorporates by reference the legal standards for anticipation and obviousness at Sections II-III(C) (pages 2-5) of the *Purdue v. Teva I* Statement of Elements.

C. Secondary Considerations

Pursuant to the Order, Teva also relies on an incorporates by reference the legal standard for secondary considerations of non-obviousness at Section III(D) (pages 5-6) of the *Purdue v. Teva I* Statement of Elements.

III. STATEMENT OF CLAIMS AND ELEMENTS

Plaintiffs assert only claim 6 of the '963 patent against Teva. Claim 6 depends from claim 1, which reads as construed by the Court:

> 1. A controlled release pharmaceutical formulation, which is not a film or comprised of layered films, comprising an effective amount of a therapeutic compound and a high molecular weight polyethylene oxide, wherein the poly(ethylene oxide) has a molecular weight of about 1,000,000 to about 10,000,000 Daltons, and wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio, by weight, of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 to about 50:50, with the poly(ethylene oxide) comprising at least 50% of the formulation.

Claim 6 adds a limitation that the controlled release pharmaceutical formulation is made by hot-melt extrusion:

> 6. The non-film controlled release pharmaceutical formulation of claim 1 wherein said formulation is prepared by a process of hot-melt extrusion.

Plaintiffs do not allege literal infringement of claim 6 because Teva does not use hot-melt extrusion to make its controlled release tablets. Instead, Plaintiffs allege infringement under the doctrine of equivalents. Plaintiffs' infringement theory will not succeed because the evidence will show the function, way, and result of the hot-melt extrusion process of claim 6 are not substantially similar to the function, way, and result of Teva's manufacturing process.

The specification of the '963 patent and the publications and testimony of its inventors demonstrate that the purpose and goal of the invention was to make controlled release matrix dosage forms, and Plaintiffs' expert Dr. Davies agrees. Unlike hot-melt extrusion, Teva manufactures its controlled release matrix tablets using a decades-old process of using a tablet press to directly compress the ingredients without heat, forming controlled release matrix tablets.

After the controlled release matrix is formed and the goals and purposes of the claimed invention of the ’963 patent have already been realized, Teva then heats the tablets.

Plaintiffs contend that the heating step in Teva’s process should be considered in the infringement analysis. However, the evidence will show that the controlled release matrix of Teva’s tablets is formed using only direct compression, and Teva has already fully achieved the goals of claim 6 of the ’963 patent before it applies any heat to the tablets. Therefore, because Teva’s direct compression process achieves the ’963 patent’s purpose of forming a controlled release matrix, the proper comparison is Teva’s controlled release matrix tablets formed by direct compression without heat versus the hot-melt extrusion process of claim 6. Using this comparative framework, the inventors of the ’963 patent and Dr. Davies agree that direct compression is not equivalent to hot-melt extrusion.

But, even if the heating step is considered in the analysis, the evidence will show that Teva’s heated tablets are not substantially the same as tablets formed by hot-melt extrusion.

A. Teva’s Products Do Not Infringe Claim 6 Under the Doctrine of Equivalents

1. The Function of Claim 6 is Not Substantially the Same as the Function of Teva’s Process

The function of claim 6 of the ’963 patent is to form a controlled release matrix with simultaneous mixing, melting and pressure. The purpose of the ’963 patent is to make controlled release matrix dosage forms, as shown by the ’963 patent itself, multiple publications of the inventors of the ’963 patents, testimony of the inventors, and statements by Plaintiffs’ expert Dr. Davies. The function of the hot-melt extrusion in claim 6 of the ’963 patent is to prepare the controlled release matrix with simultaneous mixing, melting, and application of pressure to the ingredients. Hot-melt extrusion simultaneously mixes, melts, and applies pressure to the ingredients by mixing the powder ingredients, feeding the ingredients into the barrel of a heated

extruder, and moving the melted material through the extruder barrel with the mixing and shearing action of a rotating screw. The melted material is pushed through a die at the end of the extruder. The resulting controlled release matrix is then cooled, and can be shaped into tablets or other dosage forms.

The function of Teva's process is substantially different because Teva forms the controlled release matrix using the well-known process of direct compression ***without heat***. As the inventors of the '963 patent have stated, direct compression without heat is a "traditional" and among the "most widely used processes" to make controlled release dosage forms. Teva employs this "traditional" process to make its controlled release tablets. The evidence, including dissolution or drug release data, demonstrates that the release profiles of Teva's compressed tablets are equivalent to the release profiles of the tablets after the heating step. The evidence will also show that Teva's tablets already match the controlled release dissolution profiles of OxyContin® after direct compression and before any heat is applied to the tablets. This evidence will confirm that the heating step in Teva's process is not relevant to the formation of a controlled-release matrix.

2. The Way of Claim 6 is Not Substantially the Same as the Way of Teva's Process

The way claim 6 of the '963 patent achieves the function is with hot-melt extrusion, which involves mixing and loading the ingredients into an extruder, moving the ingredients through the heated barrel of the extruder with the shearing and mixing action of one or more rotating screws, and pushing the material through the die at the end of the barrel. Teva's process of direct compression to form controlled release tablets is not substantially similar. The ingredients are mixed and then compressed in a rotary press. The inventors of the '963 patent

have repeatedly distinguished their invention from the direct compression process that Teva uses to form its controlled release tablets.

Even considering the heating step used by Teva after it has formed controlled release matrix tablets, Teva's process is still not substantially similar to hot-melt extrusion. Hot-melt extrusion simultaneously applies pressure and mixing to molten material. Hot-melt extrusion requires very different equipment, including an extruder, a screw, a heated barrel and a die. Teva's process does not involve the simultaneous application of pressure and heat, and does not involve any extrusion equipment.

3. The Result of Claim 6 is Not Substantially the Same as the Result of Teva's Process

Teva's controlled release tablets formed after direct compression are not substantially similar to tablets formed by hot-melt extrusion. The internal structure of tablets formed by direct compression are different from tablets formed by hot-melt extrusion. The inventors of the '963 patent themselves distinguished controlled release dosage forms made by direct compression from those made by hot-melt extrusion for these reasons.

The evidence will also show that Teva's heated tablets are not substantially the same as tablets formed by hot-melt extrusion. Tablets made by hot-melt extrusion have different properties, such as differences in homogeneity, than tablets made by direct compression followed by heating. Based on this uncontroverted evidence, Plaintiffs will be unable to satisfy their burden of proving that tablets made by hot-melt extrusion are substantially similar to tablets made by direct compression followed by curing.

B. Invalidity

Pursuant to the Order, Teva relies on and incorporates by reference the Statement of Elements relating to anticipation and obviousness set forth in Section I at pages 8-9 and Section I(B) (pages 12-15) of the *Purdue v. Teva I* Statement of Claims and Defenses.

C. Secondary Considerations of Non-Obviousness

Pursuant to the Order, Teva relies on and incorporates by reference the Statement of Elements relating to secondary considerations of non-obviousness of claim 6 of the ’963 patent in Section VII (pages 35-40) of the *Purdue v. Teva I* Statement of Claims and Defenses. In addition, to the extent Plaintiffs will offer new evidence regarding secondary considerations that was not available at the time of *Purdue v. Teva I*, Plaintiffs will be unable to show a nexus between the purported secondary considerations of Reformulated OxyContin and claim 6 of the ’963 patent.

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By: *s/ Sarah M. Stensland*

David M. Hashmall
GOODWIN PROCTER LLP
The New York Times Building,
620 Eighth Avenue
New York, NY 10018-1405
Telephone: (202) 813-8800
Facsimile: (202) 355-3333
dhashmall@goodwinprocter.com

Of Counsel:
Mark D. Schuman
Todd S. Werner
Sarah M. Stensland
Jennell C. Bilek
Christopher A. Pinahs
CARLSON, CASPERS, VANDENBURGH,
LINDQUIST & SCHUMAN, P.A.
225 South Sixth Street, Suite 4200
Minneapolis, MN 55402
Telephone: (612) 436-9600
Facsimile: (612) 436-9605
mschuman@carlsoncaspers.com
twerner@carlsoncaspers.com
sstensland@carlsoncaspers.com
jbilek@carlsoncaspers.com
cpinahs@carlsoncaspers.com

Attorneys for Teva Pharmaceuticals USA, Inc.